FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
October 16, 2013

DRAFT AGENDA

The committee will discuss the supplemental new drug application, sNDA 202057/S-005, Vascepa (icosapent ethyl) Capsules, submitted by Amarin Pharmaceuticals Ireland Ltd. Vascepa is currently approved as monotherapy for the treatment of severe hypertriglyceridemia. This supplemental application proposes concomitant use with an inhibitor of HMG-CoA reductase (statin) to reduce triglycerides (TG), non-high-density lipoprotein cholesterol (non-HDL-C), apolipoprotein B (Apo B), low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC) and very-low-density lipoprotein cholesterol (VLDL-C) in adults with mixed dyslipidemia and coronary heart disease (CHD) or a CHD risk equivalent.

8:00 a.m.	Call to Order and Introduction of Committee	**Robert J. Smith, MD** Acting Chairperson, EMDAC
8:10 a.m.	Conflict of Interest Statement	**Stephanie L. Begansky, PharmD** Acting Designated Federal Officer, EMDAC
8:20 a.m.	**FDA INTRODUCTORY REMARKS**	**Eric Colman, MD** Deputy Director Division of Metabolism and Endocrinology Products (DMEP) Office of Drug Evaluation (ODE) II Office of New Drugs (OND) Center for Drug Evaluation and Research (CDER) Food and Drug Administration (FDA)
8:30 a.m.	**SPONSOR PRESENTATIONS**	**Amarin Pharmaceuticals Ireland, Ltd.**
	Introduction and Regulatory History of Vascepa	**Peggy Berry, MBA** VP, Regulatory Affairs & Clinical Quality Amarin Pharma, Inc.
	UnMet Need in Patients with Mixed Dyslipidemia	**Mike Miller, MD, FACC, FAHA** Professor Departments of Medicine, Epidemiology & Public Health University of Maryland School of Medicine Director, Center for Preventive Cardiology University of Maryland Medical Center

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	SPONSOR PRESENTATIONS (CONT.)	
	Efficacy of Vascepa in the ANCHOR study	**Declan Doogan, MD** Chief Medical Officer Amarin Pharma, Inc.
	Safety of Vascepa in the ANCHOR study & REDUCE-IT Overview	**Steven Ketchum, PhD** President of R&D, SVP Amarin Pharma, Inc.
	Vascepa Benefit-Risk Discussion	**Harold Bays, MD, FTOS, FACE, FNLA** Louisville MARC Research Center Louisville, KY
9:45 a.m.	Clarifying Questions	
10:15 a.m.	**BREAK**	
10:30 a.m.	**FDA CLINICAL REVIEW**	**Mary D. Roberts, MD** Clinical Reviewer DMEP, ODE II, OND, CDER, FDA
11:15 a.m.	Clarifying Questions	
11:45 a.m.	**LUNCH**	
12:45 p.m.	Open Public Hearing	
1:45 p.m.	Questions to the Committee/Committee Discussion	
3:00 p.m.	**BREAK**	
3:15 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	